

### **REMARKS**

Prior to the filing of this response, claims 1-5, 17-19, 21-32, 41-42, 44-47 and 67-68 were pending in the application.

In this response, independent claims 1 and 29 are amended to clarify that the detachment mechanism actuates the fixation mechanism to selectively self-detach the device from a surface of a body lumen. In this application, the term self-detach means detachment without the need for endoscopic intervention.<sup>1</sup> Independent claim 67 is also amended to provide proper antecedent basis for the claim terms.

In view of the above amendments and the following remarks, Applicants respectfully request further examination of the application and reconsideration of the rejections set forth in the Office Action dated July 15, 2008.

#### **I. Allowable Subject Matter**

In paragraph 18 of the Office Action, the Examiner indicated that claims 67-68 are allowed. In paragraph 19 of the Office Action, the Examiner also indicated that claims 4-5 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants wish to thank the Examiner for these indications of allowability.

#### **II. Claim Rejection Under 35 U.S.C. § 102**

In paragraph 7 of the Office Action, page 3, claims 1-3, 17, 24-27, 29-31, 41 and 45-46 are rejected under 35 U.S.C. § 102(e) as anticipated by Cartledge et al. (US 7,175,660; hereafter Cartledge). This rejection is respectfully traversed for the reasons that follow. The Examiner has failed to establish that the Cartledge reference discloses each and every element of the presently claimed invention.

Independent claim 1 requires a controlled detachment mechanism that mechanically actuates a fixation mechanism to selectively self-detach the device housing from a surface of a

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<sup>1</sup> See, for example, application as filed, paragraph 50.

body lumen. Independent claim 29 also requires similar elements. The device shown in Cartledge fails to teach or suggest such a controlled detachment mechanism.

In paragraph 7 of the Office Action, the Examiner notes that the device in Cartledge includes a fixation mechanism to attach the device to a surface within the body lumen, and in support of this position cites the adjustment means, col. 15, lines 47-57. In paragraph 7 the Examiner contends that the device in Cartledge includes “a controlled detachment mechanism (adjustment mechanism) mechanically actuated to selectively self-detach the device housing from the surface of the body lumen (adjustment mechanism controls the means to remotely change the shape/size and including complete detachment and removal from the body; see above citations).”

In view of the above, the Examiner contends that the adjustment means in Cartledge perform the functions of both the fixation mechanism and the controlled detachment mechanism of the presently claimed device. Applicants respectfully disagree.

To attach the implant device 10 of Fig. 1 to a surface of the body lumen, Cartledge utilizes a fixation means such as a suture 35.<sup>2</sup> Cartledge teaches that the implant 100 of Figs. 4-5 is sutured to the heart.<sup>3</sup> The implant 645 of Figs. 12-16 includes release elements 660 that releaseably detach the implant 645 from the delivery system, but retention barbs 646 on the implant 645 are not retractable or controlled by the release elements 660 to release the implant 645 from the surface of the body lumen.<sup>4</sup> Similarly, the implants 700 in Figs. 21-24 include an arrangement of unidirectional retention barbs 710 with terminal hooks 775 that can be used to irreversibly seat the implant in the tissue at the time of device deployment.<sup>5</sup> But, once so seated, the Cartledge reference does not teach or suggest that the device can be selectively detached as presently claimed.

The adjustment means in Cartledge, when operated by an adjustment mechanism, is capable of altering the shape and/or size of the implant to provide secure adjustment and/or retention of the device to a desired portion of the body.<sup>6</sup> However, the Examiner has identified

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<sup>2</sup> Cartledge, col. 7, line 7; Figs. 2-3.

<sup>3</sup> *Id.*, at col. 7, line 42.

<sup>4</sup> *Id.*, at col. 9, lines 59-60; col. 10, lines 1-11.

<sup>5</sup> *Id.*, at col. 12, lines 40-59.

<sup>6</sup> *Id.*, at col. 15, lines 28-30.

no teaching in Cartledge that the adjustment means can be used to mechanically self-detach the implant from body tissue as presently claimed. Instead, Cartledge states that the implant body may be provided with one or more attachment members to facilitate attachment of the implant to the native recipient site. Examples include sutures and mechanical tissue interfaces such as adhesives.<sup>7</sup> Cartledge fails to teach or suggest that any of these methods of attachment may be mechanically reversible in response to a controlled detachment mechanism as required by the present claims.

In view of the above, the Examiner has failed to establish that the cited Cartledge reference discloses a fixation mechanism that is mechanically actuated and self-detachable in response to a controlled attachment mechanism as presently claimed. Since the cited reference fails to disclose, teach or suggest this element of the present independent claims 1 and 29, the subject matter of the present claims 1-3, 17, 24-27, 29-31, 41 and 45-46 is neither anticipated under 35 U.S.C. § 102(e) nor *prima facie* obvious under 35 U.S.C. § 103(a) over Cartledge. Reconsideration and withdrawal of the cited anticipation rejection are respectfully requested.

### **III. Claim Rejections Under 35 U.S.C. § 103(a)**

On page 4 of the Office Action, paragraph 9, claims 3 and 31 are rejected under 35 U.S.C. § 103(a) over Cartledge in view of Kilcoyne et al. (US 6,689,056; hereafter Kilcoyne).

In paragraph 10 of the Office Action, claims 19, 22-23 and 42 are rejected under 35 U.S.C. § 103(a) over Cartledge in view of Imran et al. (US 6,535,764; hereafter Imran).

As noted above in Section II of this response, the primary reference Cartledge fails to disclose, teach or suggest an element of independent claims 1 and 29, namely a fixation mechanism that is mechanically actuated and self-detachable by a controlled attachment mechanism. The Examiner has not established that the secondary references Kilcoyne and Imran teach or suggest such a fixation mechanism and controlled attachment mechanism, and for this reason claims 3, 19, 22-23, 31 and 42 are not *prima facie* obvious under 35 U.S.C. § 103(a) over the combined teachings of Cartledge and either of Kilcoyne or Imran. Reconsideration and withdrawal of the obviousness rejections are respectfully requested.

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<sup>7</sup> Cartledge, at col. 16, lines 1-15.

**IV. Rejections for Obviousness-type Double Patenting:**

A. In paragraph 12 of the Office Action, claims 1-3, 17-19, 24-27, 29-31, 45-46 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of US 6,689,056 to Kilcoyne et al (hereafter Kilcoyne). The Examiner contends that the invention claimed in the present application is “merely generic” to the species claimed in Kilcoyne. This rejection is respectfully traversed for the reasons that follow.

Claims 1-26 of Kilcoyne are directed to a method for attaching a device to a tissue surface inside a patient. In this method a device includes a housing with concavity, and a pin that is axially moveable from a retracted position to a position extending at least part way across the concavity. Tissue is drawn into the concavity, and the pin is advanced through the tissue to retain the device at an attachment site. Claims 5, 9 and 24 specify that the pin may be made of a degradable or a dissolvable material, and this degradation process may be utilized to control the release the device from the attachment site.

As noted above in Sections II and III of this response, the present independent claims 1 and 29 require a fixation mechanism that is mechanically actuatable and self-detachable by a controlled detachment mechanism. A fixation mechanism mechanically actuatable by a controlled detachment mechanism is neither taught nor suggested in the claims of Kilcoyne. While both the claims of Kilcoyne and the present application describe methods for controlled detachment of a medical device from body tissue, the present claimed apparatus provides a number of advantages of the approach described in Kilcoyne, including the possibility of more rapid detachment and more precise control of the timing of detachment. The present mechanical approach is completely different from the selection of degradable materials in the claims of Kilcoyne. The Examiner has not articulated any rational reason that a skilled artisan would modify the degradable materials in Kilcoyne to provide the presently claimed mechanical detachment apparatus. For at least this reason, the subject matter of the present claims would not be obvious under 35 U.S.C. § 103(a) over the claims of Kilcoyne. Reconsideration and withdrawal of the rejection for obviousness-type double patenting are respectfully requested.

B. Claims 1, 17-18, 24-27, 29, 45-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 15-17, 62-87 of copending Application No. 10/833,776.

Claims 1-3, 17-18, 24-27, 29-31, 45, 46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 10-11, 13-16, 55-58, 61-66 of copending Application No. 10/687,296.

Claims 1-3, 17-19, 24-27, 29-31, 45, 46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 55-58, 66, 69, 71, 73 of copending Application No. 10/896,553.

Claims 1-3, 17-18, 24-31, 45, 46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-53 of copending Application No. 10/835,425.

Applicants submit that upon entry of the amendments set forth herein, the provisional rejections under the judicially created doctrine of obviousness-type double patenting are the only rejections remaining in this application. Applicants therefore respectfully request that the Examiner withdraw the provisional double patenting rejections.<sup>8</sup>

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<sup>8</sup> See MPEP 804(I)(B).

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778.

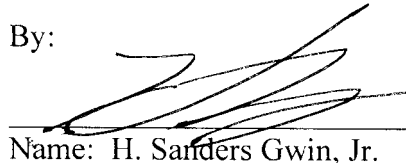
If questions remain regarding the above, please contact the undersigned.

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